IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Upit: 1812 In re Application of: WALLACH et al Serial No.: 08/485,129 Examiner: R. Schwadron Filed: June 7, 1995 Washington, D.C. FOR: TUMOR NECROSIS FACTOR BINDING PROTEI Atty.'s Docket: WALLACH=5B GCT 0 8 1996 Date: October 7, 1996 THE COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 Transmitted herewith is an [ ] Amendment [ ] the above-identified application. [ ] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted. [ ] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed. [XX] No additional fee is required. The fee has been calculated as shown below: SMALL ENTITY OTHER THAN A SMALL ENTITY (Col. 1) (Col. 3) (Col. 2) RATE ADDĮĮĮONAL RATE PRESENT EXTRA ADDITIONAL AMENDMENT x 11 TOTAL MINUS \$ x 22 \$ MINUS = x 40 INDEP. \$ x 80 \$ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM +130 \$ + 260 ADDITIONAL FEE TOTAL \* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3. If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space. If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space. The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed. [XX] Conditional Petition for Extension of Time If any extension of time for a response is required applicant requests that this be considered a petition therefor. [ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below: Small Entity Other Than Small Entity Response Filed Within Response Filed Within [ ] First - \$ 55.00 First - \$ 110.00 Second - \$195.00 [ ] Second - \$ 390.00 - \$465.00 - \$ 930.00 Third [ ] Third [ ] Fourth - \$735.00 [ ] Fourth - \$1470.00 Month After Time Period Set Month After Time Period Set [ ] Less fees (\$\_\_\_\_\_) already paid for \_\_ month(s) extension of time on [ ] Please charge my Deposit Account No. 02-4035 in the amount of \$\_\_\_\_ \_\_\_\_\_. A duplicate copy of this sheet is attached. [ ] A check in the amount of \$ \_ is attached (check no. [XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR Section 1.16 and all patent processing fees under 37 CFR Section 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR Section 1.18. BROWDY AND NEIMARK

Attorneya for Applicant(s)

ROGER L. BROWDY

Registration No. 25,618

Facsimile: (202) 737-3528 Telephone: (202) 628-5197



## IN THE UNITED STATEMENT AND TRADEMARK OFFICE

In re Application of:

Art Unit: 1812

WALLACH et al

Examiner: R. Schwadron

Serial No.: 08/485,129

Washington, D.C.

Filed: June 7, 1995

October 7, 1996

For: TUMOR NECROSIS FACTOR

Atty.Docket: WALLACH=5B

BINDING PROTEIN II, ITS )
PURIFICATION AND ANTIBODIES)

THERETO

## RESPONSE

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

The present communication is responsive to the official action of September 5, 1996. Claims 11-14 and 33-45 presently appear in this case. The examiner has required restriction. No claims have yet been examined on the merits. Reconsideration and withdrawal of the restriction requirement and examination of all the claims in this case on the merits is hereby respectfully urged.

The examiner has required restriction to one of the following inventions under 35 USC 121:

Group I, including claims 11-13, 33-38, 40, 41, 43 and 44, drawn to DNA, expression vectors containing said DNA, and host cells containing said expression vectors; and

Group II, including claims 14, 39, 42 and 45, drawn to a process for producing a protein.

The examiner states that the inventions are related as product and process of use and that the product as claimed can be

În re USSN 08/485,129

used in a materially different process, such as preparation of DNA probes that can be used in hybridization assays to detect TBP-II DNA in cells. This restriction requirement is respectfully traversed.

The process claims of Group II are drawn to the method of use of the host cell claims. The host cell claims are cells which contain a recombinant replicable expression vehicle. One does not use host cells with replicable expression vehicles for the preparation of DNA probes. The only viable utility for host cells with replicable expression vehicles is for the expression of the protein. This is the only practical use for such host cells and all of the claims should be examined together. The host cells cannot be directly used for the preparation of DNA probes. They contain much too much DNA unrelated to the protein of interest to be used for this purpose. Much additional processing would be required before one could obtain DNA useful as a probe. Such an indirect utility is not contemplated by MPEP §806.05(h).

Furthermore, MPEP §803 emphasizes that two criteria must be met in order for restriction to be proper. The second criteria is that there must be a serious burden on the examiner if restriction is not required. Accordingly, even if the examiner is correct that the inventions are independent or distinct, the examiner must establish he would face a serious burden if restriction is not required. Here, if the restriction requirement is not withdrawn, applicant will elect the product claims of Group I. Applicant hereby concedes that, if claims 13, 38, 41 and 44 (from which claims 14, 39, 42 and 45 are dependent, respectively)

In re USSN 08/485,129

are anticipated by or obvious over the prior art, that the process of use claims dependent therefrom are also obvious. Accordingly, no further search is necessary by the examiner in view of this admission and there can be no argument whatsoever that there is a serious burden on the examiner if restriction is not required.

Finally, the examiner's attention is invited to the Commissioner's notice appearing at 1184 OG 86 dated March 26, 1996, as well as MPEP §821.04 added by the July 1996 revision of the MPEP. Both of these provide that in restriction requirements such as this, even if the restriction requirement is found to be permissible, if applicant elects claims directed to the product and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable claim will be rejoined.

In order to be responsive, applicant hereby elects the claims of Group I for examination in this case, subject to the above traversal of the restriction requirement.

Accordingly, in summary, applicant has elected the claims of Group I for examination in this case. However, the restriction requirement should be withdrawn because the only viable, direct use of the host cells with expression vectors is in expressing the proteins. Additionally or alternatively, the restriction requirement must be withdrawn because there is no serious burden on the examiner in examining all of the claims, particularly in light of the admission which has been made in the present traversal. Finally, even if the restriction requirement is retained, it is requested that the examiner acknowledge the

In re USSN 08/485,129 procedure of MPEP §821.04, which requires that the product of use claims be rejoined once any of the product claims are found allowable. A suggestion is hereby respectfully made that any time a restriction requirement such as the present is made by the Patent and Trademark Office, the paper should advise applicant of the rejoinder procedure of MPEP §821.04 and 1184 OG 86. The examiner's attention is invited to the fact that the present application is a division of application 07/930,443. allowable protein claim has been found in the parent case, which application is now involved in an interference with the claims of

U.S. patent number 5,344,915 which is of record in this case. The interference number is 103,625.

Accordingly, withdrawal of the restriction requirement and examination of all the claims now present in the case or examination of the elected claims and rejoinder of the non-elected claims following allowability of the elected claims are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.

Attorneys for Applicant(s)

By:

ROGER L. BROWDY

Registration No. 25,618

RLB:al

419 Seventh Street, N.W.

Washington, D.C. 20004

Telephone No.: (202) 628-5197

Facsimile No.: (202) 737-3528

roger\wall5b.res